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NORRIS, MCLAUGHLIN & MARCUS, PA
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NEW YORK, NY 10022

EXAMINER

ROGERS, JAMES WILLIAM

ART UNIT	PAPER NUMBER
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1618

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01/11/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/659,894	Applicant(s) VOGT ET AL.	
	Examiner James W. Rogers, Ph.D.	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 October 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2,4-13 and 15-30 is/are pending in the application.
- 4a) Of the above claim(s) 4,7,9,11-13,17,21-25 and 27 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2,4-6,8,10,15-20,26 and 28-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>07/16/2007</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of the requirement for restriction/election in the reply filed on 10/19/2007 is acknowledged. The traversal is on the ground(s) that the present restriction requirement is improper and unnecessary because the amendments to the claims merely reorganize the elements already present in claim 1. Therefore applicants surmise the scope of the claims has not changed and the examiner has already searched the entire scope of claim 28 thus there would be no burden to examine. This is not found persuasive because firstly claim 28 was not searched before by the examiner and claims 21-25 were previously withdrawn for pertaining to an unelected invention. Due to applicants amendments to the claims the claims are now drawn to an antibiotic polymer combination and a method of applying an antibiotic combination to a surface of a plastic. From the previous response to restriction requirement filed 06/12/2006 by applicants group II drawn to composites from a polymer combination were selected. Since the examiner did not search for a method of applying the polymer combination the scope of the claims the examiner must examine has changed. Thus as outlined in the new election restriction requirement filed 09/20/2007 a search between groups I and II would be a burden on the examiner.

The requirement is still deemed proper and is therefore made FINAL.

The examiner notes that in the previous response restriction requirement filed 06/12/2006 applicants elected the following species, Gentamicin as the hydrophobic antibiotic, PVC as the hydrophobic polymer, PEG as the hydrophilic polymer, the

method to form the composite consisted of immersing a plastic surface into cyclohexanone solution and drying, the type of composite was a coating and the device made was a tube. From the above restriction requirement and the species elected the following claims were withdrawn by the examiner for pertaining to unelected material, 4,7,9,11-13,17,21-25 and 27.

Claim Objections

Claim 2 is objected to because of the following informalities: "comprisng" in line 2 of the claim is misspelled. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2,4-6,8,10,15-20,26 and 28-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The boundaries for the protection sought for an antibiotic salt that is "slightly water-soluble" and antibiotic that is "readily soluble in water" are not discernible making the scope of the claims unclear and indefinite. Applicants may overcome the rejection by reciting those specific antibiotics that exhibit those solubility properties without the introduction of new matter into the claims or the specification.

Claims 2 and 28 requires that one or more hydrophilic polymers is selected from the "groups comprising polyether." However, it is unclear how a selection can be made

from one compound or from a group that is made up of one compound. Clarification is respectfully requested.

The boundaries for the protection sought for an antibiotic shaped object within claim 19 is not discernible making the scope of the claims unclear and indefinite.

Applicants may overcome the rejection by reciting specific shapes that would encompass the scope sought without the introduction of new matter into the claims or the specification.

Within claim 20 is not clear what is incorporated by the limitation of an antibiotic laminate. The limitation is also not clearly defined within applicant's specification. To the examiner laminate means to cover with a thin sheet, dividing into thin layers, combining several layers into one and comprising or compressing into a thin sheet or plate. Thus there could be several interpretations of what an antibiotic laminate could comprise, thus the scope of the claims unclear and indefinite.

Claim 29 depends upon cancelled claim 1, thus it is indefinite with respect to what claim it is limiting. The examiner believes the claim was further limiting claim 2 and examined the claim as such.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 15-16,18,20,26, 28 and 30 are rejected under 35 U.S.C. 102(b) as being anticipated by Whitbourne et al. (US 6,110,483, cited previously).

Whitbourne teaches medical devices that may/are coated with a liquid coating composition that comprises cross-linkable hydrophobic stabilizing polymers and combinations with hydrophilic polymers (including PEG), bioactive agents (including gentamicin a known aminoglycoside antibiotic) and other polymer in addition to the stabilizing polymer (including PVC). See col 1 lin 65-col 2 lin 13, col 7 lin 31-40 and col 8 lin 59-col 9 lin 5. Regarding the limitation within claim 28 that the antibiotic is suspended in a homogeneous polymer mixture, Whitbourne specifically recites that the active ingredient depending upon the solvent used can be dispersed and not dissolved within the polymer/solvent mixture, thus it is inherent that the active ingredient would be suspended in the polymer once the solvent was evaporated since the active ingredient can be present as discrete particles. See col 8 lin 9-24. It is also inherent that since the polymer coating of Whitbourne contains the same ingredients as applicants claimed invention the composition will have the same settling properties, therefore the active ingredients will inherently form a suspension with the polymer. The solution or liquid coating composition is prepared in solvents including cyclohexanone and THF that are removed by evaporation. See col 3 lin 14-19, col 8 lin 9-24 and col 9 lin 42-49. Whitbourne teaches several ways in which the coating may be applied by various techniques including dip, pour, pump, spray, brush, wipe, or other methods known to those in the art. See col 7 lin 20-24.

Response to Arguments

Applicant's arguments filed 07/16/2007 have been fully considered but they are not persuasive. Applicants assert that Whitbourne does not teach that elements a, b and c are suspended in element d to form a composite. As detailed above since Whitbourne teaches the same polymers and active ingredients in a polymer composition as applicants it is inherent that the same composition will be capable of forming a suspension.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 2,4-6,8,10,15-20,26 and 28-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Whitbourne et al. (US 6,110,483) in view of Watanakunakorn et al., ("Effects of combinations of clindamycin with gentamicin, tobramycin, and amikacin against *Staphylococcus aureus*," in *Journal of Antimicrobial Chemotherapy* (1980), Vol. 6, No. 6, abstract of pp. 785-791) in view of McGhee (US 6,110,483) in view of Rozzi et al. (US 2003/0138492 A1).

Whitbourne is disclosed above. While Whitbourne discloses compositions that comprises gentamicin antibiotic in combination with PVC and polyethylene glycol for coating medical devices Whitbourne does not contain another antibiotic that is an aminoglycoside, lincosamide, tetracycline or β -lactams. Watanakunakorn (abstract of pages 785-791) discloses synergism between clindamycin and gentamicin or tobramycin or amikacin. And regarding the relative solubilities of these antibiotics, it is known that clindamycin, a lincosamide antibiotic and gentamycin, an aminoglycoside antibiotic have different solubilities and the different solubilities would lead to different release from the same polymer while the polymers also contribute to the release profile of drugs. Therefore, the artisan upon seeing the references together could have envisioned the combination of clindamycin and gentamicin as an antibiotic in the formulation and expect the two antibiotics to act synergistically against the bacterial infection being treated. It is generally considered to be prime facie obvious to combine

compounds each of which is taught by the prior art to be useful for the same purpose in order to form a composition that is to be used for an identical purpose. It therefore follows that the instant claims define *prime facie* obvious subject matter.

Whitbourne and Watanakunakorn are disclosed above, neither reference discloses the use of antiphlogistic, sulfonamides and anesthetics as claimed within claim 10 with the antibiotic. Mcghee discloses coatings for medical devices that contain antimicrobials including aminoglycosides such as gentamicin in combination with additives including anesthetics. See abstract, [0011], [0013],[0043] . It would have been obvious for one of ordinary skill in the art at the time of applicants invention to include an anesthetic in the coating composition of Whitbourne in view of Mcghee with the expectation that that the implant will deliver antibiotic to control infection and also deliver an anesthetic to minimize patients discomfort during healing. Thus claim 10 would have been *prima facie* obvious since all the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention.

Whitbourne and Watanakunakorn are disclosed above, neither reference discloses the use of PEG within applicants claimed range for dependent claims 6 and 8. Rozzi discloses coatings for medical devices that use PEG with molecular weights between 200-600 D. Thus it would have been obvious to one of ordinary skill in the art at the time of the invention to use the MW of PEG disclosed within Rozzi for the PEG

disclosed within Whitbourne without a fundamental change to the structure of the coating and would have yielded predictable results to the artisan.

Conclusion

No claims are allowed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to James W. Rogers, Ph.D. whose telephone number is (571) 272-7838. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read 'MH', with a long horizontal line extending to the right.

MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER